ROSTER

EAR, NOSE AND THROAT DEVICES PANEL

AUGUST 16, 2002 MEETING

CHAIR

A. JULIANNA GULYA, M.D.

Dr. A. Julianna Gulya is the Chief of the Clinical Trials, Epidemiology and Biostatistics Section of the National Institute on Deafness and Other Communication Disorders (NIDCD) of the National Institutes of Health in Bethesda, MD. She came to NIH from a Professorship in Otolaryngology-Head and Neck Surgery at the Georgetown University Hospital Medical Center. She received her MD degree with Distinction in Research from the University of Rochester School of Medicine and Dentistry in Rochester, NY. She was appointed a Clinical Fellow in Surgery at the Harvard Medical School while a Surgical Junior Resident at Beth Israel Hospital and completed an otolaryngology residency at the Massachusetts Eye and Ear Infirmary, Boston, MA, and an otology/neurotology fellowship at the EAR Foundation/Baptist Hospital in Nashville, TN. Dr. Gulya is member of the editorial board of the American Journal of Otology, Otolaryngology -- Head and Neck Surgery, and The Laryngoscope as well as providing her expertise as a reviewer for The Annals of Otology, Rhinology, and Laryngology, the Archives of Otolaryngology-Head & Neck Surgery and the Journal of Neurosurgery among others. She has published on a variety of topics including sudden sensorineural hearing loss, endolymphatic hydrops and neoplasms affecting hearing and balance.

VOTING MEMBERS

HOWARD W. FRANCIS, M.D.

Dr. Howard Francis is an Assistant professor, with the Division of Neurotology and Skull Base Surgery, Department of Otolaryngology-Head and Neck Surgery at the Johns Hopkins University School of Medicine, Baltimore, MD. He received his MD degree with honors from the Harvard-Massachusetts Institute of Technology Division of Health, Science and Technology, Harvard Medical School, Boston, MA and completed his residency and a fellowship in Otology and Neurotology, in the Department of Otolaryngology-Head and Neck Surgery at Johns Hopkins. His research and special interests are the management of deafness in young children and the mechanism of cochlear dysfunction secondary to aging and noise injury. Dr. Francis has contributed his expertise as an author of many journal publications and book chapters.

LINDA J. HOOD, PhD

Dr. Linda J. Hood is a Professor at the Kresge Hearing Research laboratory of the South, Department of Otorhinolaryngology, Louisiana State University Health Sciences Center in New Orleans, Louisiana. She received a master's degree in Audiology from Kent State University, a PhD in Hearing Science from the University of Maryland and completed an NIH Post-Doctoral Fellowship at Kresge Laboratory in New Orleans. Research, clinical interests, publications and presentations include the areas of auditory evoked potentials, otoacoustic emission, function of the efferent auditory systems, hereditary hearing loss, central auditory processing, development of hearing, aging of the auditory system, cochlear implants and comparative hearing studies. In addition to research and teaching, Dr. Hood is Director of the Cochlear Implant Program at LSU Health Sciences Center, a member of two NIH working groups on Early Identification of Hearing Impairment and Genetic Testing of Populations with Hearing Impairment. She is a Past President of the American Academy of Audiology.

HERMAN A. JENKINS, M.D.

Dr. Herman A. Jenkins, is the recently appointed Chairman of the Department of Otolaryngology at the University of Colorado Health Sciences Center in Denver, Colorado. He received his medical degree from the Vanderbilt University School of Medicine in 1970, then completed a surgical internship and residency in otolaryngology-head and neck surgery at the UCLA Center for Health Sciences. He completed a clinical and research fellowship in Neurotology with Professor Dr. Ugo Fisch at the University Hospital of Zurich, Switzerland before joining the faculty at Baylor College of Medicine in Houston, TX where he has recently served as a professor in the Department of Otolaryngology. Dr. Jenkins' clinical practice has focused in otology and neurotology, combining the evaluation and management of vestibular disorders with surgery of the ear and lateral skull base. As Director of the Center for Balance Disorders at Baylor, Dr. Jenkins was responsible for coordinating research in the neurodiagnostic techniques in human imbalance and vestibular compensation

PAUL R. KILENY, Ph.D.

Dr. Paul Kileny is a Professor of Otorhinolaryngology and Director of the Division of Audiology and Electrophysiology at the University of Michigan School of Medicine in Ann Arbor. He received his MA from Tel-Aviv University, Israel and his Doctorate in Audiology with an emphasis in neurophysiology from the University of Iowa. Dr. Kileny is on the editorial boards of the Journal of Speech and Hearing Research and Human Communication and on the review boards of The American Journal of Audiology, American Journal of Otology, Electroencephalography and Clinical Neurophysiology and Otolaryngology – Head and Neck Surgery among others. His current research interests include pediatric cochlear implant issues and aspects of hearing loss detection in newborns and infants. Dr. Kileny has authored numerous journal articles and book chapters and has lectured extensively nationally and internationally.

SIGFRID D. SOLI, Ph.D.

Dr. Soli is Vice President, Technology Transfer, and Head, Department of Human Communication Sciences and Devices at the House Ear Institute in Los Angeles, CA. He received his Ph.D. in experimental psychology from the University of Minnesota, Minneapolis while at their Center for Research in Human Learning. Dr. Soli was previously a member of the research staff of the Biosciences Laboratory, 3M Company, where he developed cochlear implant and hearing aid technologies. He was also on the faculty of the Department of Psychology, University of Maryland before his work at 3M. He is a Fellow of the Acoustical Society of America, and a previous Chair of the Speech Communication Technical Committee of that Society. His published research and patents are in the area of speech communication, and the effects of hearing impairment on speech communication. He has served as consultant to the National Institutes of Health and to several private industries on issues related to the design, development, and evaluation of diagnostics and prosthetic devices for hearing impaired individuals.

DEBARA L. TUCCI, M.S., M.D.

Debara L. Tucci is Associate Professor of surgery in the Division of Otolaryngology - Head and Neck Surgery at Duke University Medical Center. Dr. Tucci received her M.S. degree in Audiology at the University of Michigan, her M.D. from the University of Virginia, and completed a fellowship in Otology, Neurotology and Skull Base Surgery at the University of Michigan. In addition to her research in clinical otology and neurotology, her interests include the study of central auditory system development and changes in auditory anatomy and function following conductive hearing impairment, using an animal model for which she was awarded the Edmund Prince Fowler award for excellence in basic science research from the Triological Society (1998). Dr. Tucci has served as a peer reviewer for numerous journals in the fields of otolaryngology, audiology and hearing science and currently serves on the Editorial Board of the journal Otology & Neurotology, and formerly served as section editor for otology and medical issues for Ear & Hearing (1994-2000). She Dr. Tucci is a member of the Communicative Disorders Review Committee for the National Institute on Deafness and other Communicative Disorders (NIDCD) of the National Institutes of Health. Dr. Tucci is an elected fellow of the Triological Society, the American Otological Society, American Neurotology Society, the American Academy of Otolaryngology-Head and Neck Surgery, the American College of Surgeons, and is President Elect of the American Auditory Society.

NON-VOTING CONSULTANTS

BRENT A. BLUMENSTEIN, Ph.D.

Dr. Brent Blumenstein is a biostatistician and clinical trialist with special focus on the architecture and conduct of multisite clinical trials. Dr. Blumenstein was trained at Emory University, and has been on the faculty at Emory University, University of Washington, Fred Hutchinson Cancer Research Center, Northwestern University, and Duke University. His primary activities have been focused on multisite clinical trials sponsored by the National Cancer Institute, but he also has extensive experience as a consultant working on clinical trials done in support of product registration. His particular areas of statistical expertise include survival analysis, clinical trial design, and evaluation of diagnostics. His particular areas of clinical application include cancer, particularly urologic cancers, surgery, diagnostics, prognostic markers, medical devices, hypertension, and diabetes. He is also an expert in the engineering and management of systems for the collection of medical research data. Recently Dr. Blumenstein formed his own company, TriArc Consulting. He currently serves on the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee at FDA.

ROBERTO A. CUEVA, M.D., FACS

Dr. Cueva is the co-director and founder of the Skull Base Surgery Service at the Southern California Permanente Medical Group and as an Associate Clinical Professor he co-directs the UC San Diego fellowship program in Otology, Neurotology and Skull Base Surgery. Dr. Cueva completed his medical degree at the University of California at San Francisco and a residency in Otolaryngology-Head and Neck Surgery at the University of California at San Diego. He completed a fellowship in Otology, Neurotology, and Skull Base Surgery at the EAR Foundation in Nashville, TN under the direction of Drs. Michael Glasscock and C. Gary Jackson. As a highly specialized ear and skull base surgeon he has advanced the art of intra-operative monitoring of the cochlear nerve during acoustic tumor surgery with this invention of the Cueva Cranial Nerve Electrode. He also has contributed his considerable expertise to the otolaryngological community through lectures, books or book chapters, and peer-reviewed journals.

DONALD K. EDDINGTON, Ph.D.

Dr. Eddington is the Principal Research Scientist at the Research Laboratory of Electronics at the Massachusetts Institute of Technology, and the Director of the Cochlear Implant Laboratory at the Massachusetts Eye & Ear Infirmary in Boston, MA. He completed an undergraduate degree in electrical engineering, a Ph.D. in medical computing and biophysics from the University of Utah and postdoctoral training in auditory physiology from MIT. His research focuses mainly on the development of neural prostheses including the restoration of hearing using intracochlear electric stimulation (cochlear implants), and has expanded to include visual, vestibular and voice prostheses as he leads a group of scientists, clinician and engineers in establishing the Neural Prostheses Research Center . In addition to the more fundamental laboratory studies, Dr. Eddington has also contributed to the design of implantable electrodes and wearable sound processing/ stimulation systems. He is internationally recognized for his expertise and has presented and published his work extensively.

JOSEPH WALTON HALL, III

Dr. Joseph Hall is a Professor and Chief of Audiology, Department of Otolaryngology - Head and Neck Surgery at the University of North Carolina in Chapel Hill. He received a BS in Psychology from the College of William and Mary in 1972 and a PhD in Psychology from the University of North Carolina at Greensboro in 1976, concentrating on the psychology of auditory perception. Because of his developing interest in the field of hearing loss, he obtained an additional Master's degree in Audiology from the University of North Carolina at Chapel Hill. Following the completion of a post-doctoral fellowship at the Duke University Center for the Study of Aging, he helped launch the Medical Research Council at the Institute of Hearing Research in Nottingham, England where he performed his initial research on Comodulation Masking Release. Dr. Hall has continued to research the perceptual effects of otitis media and the ability of cochlear hearing-impaired patients to hear in noisy backgrounds. He is a member of the Editorial Boards of the Journal of Audiology Neuro-otology and the Journal of the American academy of Audiology. Dr. Hall has published extensively in peer-reviewed journals and authored many book chapters. He is nationally and internationally recognized for his research.

BRENDA L. LONSBURY-MARTIN, Ph.D.

Dr. Brenda Lonsbury-Martin is a Professor of Otolaryngology at the University of Colorado Health Sciences Center in Denver and the Vice-Chair for Research in the Department of Otolaryngology. Dr. Lonsbury-Martin trained in the medical neurosciences at the Oregon Health Sciences University in Portland and completed postdoctoral fellowships in the hearing sciences at the University of California/Irvine and the University of Washington. For the past 17 years Dr. Lonsbury-Martin and her colleagues have been developing procedures to measure otoacoustic emission, that can be used to evaluate , screen, and monitor the healthiness of the hearing portion of the inner ear, in a number of experimental models of deafness. Her current program of research focuses on establishing these laboratory-based measures as useful clinical assessors of hearing capability, particularly with respect to detecting the early onset stages of noise and ototoxic drug induced hearing losses. Dr. Lonsbury-Martin is the associate editor for the Journal of the Acoustical Society of America and serves on the editorial boards of Journal of the American Academy of Audiology, Journal of Otology and Neurotology and Hearing Research. In addition, she serves as a member the scientific review committees for several private foundations and participates as a member of many working committees for several professional societies in her field. She has published extensively and has received numerous honor for her professional contributions.

BRIAN E. WALDEN, Ph.D.

Dr. Brian Walden is Director of Research, in the Army Audiology and Speech Center at Walter Reed Army Medical Center in Washington, DC. He received his Ph.D. from Purdue University, majoring in Audiology and speech sciences, with a minor in veterinary medicine. In this role, he directs one of the foremost hearing and speech research programs in the country, and has personally authored more than 200 journal articles, book chapters and professional papers. He has served in a variety of advisory, consultative and editorial position with professional organizations, the National Academy of Sciences, and National Science Foundation, the Department of Education and the Federal Trade Commission. Dr. Walden has received numerous awards and other recognition for his distinguished career as a scientist, most recently receiving the James F. Jerger Career Research Award from the American Academy of Audiology.

CONSUMER REPRESENTATIVE

CATALINA E. GARCIA, M.D.

Dr. Catalina Garcia is a private practicing anesthesiologist with the Dallas Anesthesiology Group of Dallas, TX and a member of Southwest Anesthesia Consultants. She received her MD from the University of Texas, Southwestern Medical School in Dallas. She has been a member of the National Science Foundation/ National Air and Space Administration's Model Institutions in Excellence Leadership Council, Vice Chairman of the American Medical Women's Association, and an alternate delegate to the Texas Medical Association's house of delegates. Dr. Garcia is currently a member of the Center for Health Policy Development, and is active in many health initiative organizations for Hispanic women at the municipal, state, and national levels.

INDUSTRY REPRESENTATIVE

R. Michael Crompton, JD, MPH, RAC

Mr. Crompton is the Vice President for Regulatory and clinical Affairs and Quality Assurance for Odyssey Technologies, Inc. of Los Gatos, California. He received a B.S. in biochemistry and a Masters in Public Health (Biomedical Sciences) from the University of California, Berkeley. In addition he received his J.D. from the University of San Francisco School of Law and is a member of the California Bar Association. His varied experience in the regulatory, clinical affairs and quality control aspects of the device industry and his training as a JD and MPH have given him the skills necessary to represent manufacturers to the Agency. His past tenure with Symphonix has provided him with valuable knowledge about the Ear, Nose and Throat segment of the medical device industry and given him a sense of hearing related issues that can be a valuable asset to a panel that will be considering predominantly hearing devices at future meetings. Through his past interactions with the Agency he is known and respected as a dedicated, knowledgeable and forthright person.